

REMARKS

Claims 18-60 are pending in this application. With this response, independent claims 18, 26, 42, 47, and 52 have been amended. No new matter is added by amendment. Support for the amendments can be found at least at the first full paragraph of p. 9 of the specification. Reconsideration of the claims as amended, in light of the remarks that follow, is respectfully requested.

Rejections over Humes (U.S. 5,911,704)

The Examiner has rejected claims 18-31, 35-56, 59, and 60 under 35 U.S.C. § 102(b) as being anticipated by Humes. Applicant has amended claims 18, 26, 42, 47, and 52 to patentably distinguish over Humes, both alone and in combination with the other prior art of record.

In particular, claim 18 has been amended to recite that the inventive method includes eluting a bioactive substance from an eluting material ***“into blood flowing through the eluting material.”*** Humes does not disclose or suggest a method that includes eluting a bioactive substance from an eluting material ***into blood flowing through an eluting material***, as is recited in claim 18 as amended.

Instead, Humes discloses a capsule that “encloses viable cells which produce and secrete [a] preselected molecule into blood ***passing the capsule***” (abstract, emphasis added). According to Humes, the capsule includes either a single hollow fiber or a bundle of hollow fibers made from a semipermeable membrane, and:

The semipermeable membrane preferably has pores of a size sufficient to permit the diffusion of a pre-selected molecule therethrough but yet small enough to exclude the passage of cells therethrough. The pores preferably are designed to permit the pre-selected molecule produced by the cells to diffuse directly into the blood stream passing the hollow fiber while preventing the cells from migrating out of the hollow fiber and into the systemic circulation. More specifically, the pores preferably are dimensioned to allow solutes having a molecular weight of less than about 150 kilo daltons to pass therethrough ***while excluding agents in the blood stream, for example, proteins, specifically,***

antibodies and cytolytic factors secreted by lymphocytes, or cells, specifically, macrophages and lymphocytes, which if allowed to pass through the pores from the blood stream into the hollow fiber may be detrimental to the viability of the cells enclosed therein (col. 3, lines 16-32, emphasis added).

Humes thus discloses specifically designing a capsule so as to have a semipermeable membrane that prevents blood from flowing through the capsule. Instead, Humes discloses that the blood merely passes by the capsule – directly contrary to the requirement of eluting a bioactive substance from an eluting material ***“into blood flowing through the eluting material,”*** as is recited in claim 18 as amended. Thus, Humes does not anticipate claim 18 as amended, nor any claims depending therefrom.

The other independent claims have been amended to recite analogous features, and thus are not anticipated by Humes for at least the reasons given above. For example, claim 26 as amended is directed to an intravascular device that includes “an eluting material adapted to elute the bioactive substance, which when introduced into the blood vessel is retained by the anchor and ***releases the bioactive substance into blood flowing therethrough.***” Claim 42 as amended is directed to a method including introducing into the blood vessel an eluting material that ***“elutes the bioactive substance into blood flowing through the eluting material.”*** Claim 47 as amended is directed to an anchor that includes “a second element adapted to couple with an eluting material, the eluting material adapted to ***elute a bioactive substance into blood flowing therethrough.***” Claim 52 as amended is directed to an apparatus that includes “a second element comprising an eluting material adapted to ***elute a bioactive substance into blood flowing therethrough.***” As Humes does not disclose or suggest any methods, devices, or apparatus that include eluting a bioactive substance from an eluting material into blood flowing therethrough, Humes does not anticipate any of independent claims 26, 42, 47, or 52 as amended, or claims depending therefrom.

Rejections over Humes in view of Leong (WO 95/26168)

The Examiner has rejected claims 32-34, 57, and 58 under 35 U.S.C. § 103(a) as being unpatentable over Humes in view of Leong.

Leong discloses a “structurally rigid, highly porous foam graft suitable for culture of transplanted cells seeded therein (p. 5). Leong discloses that the three dimensional polymer foam:

...provides a sturdy scaffold for to the transplanted cells and a means of organization to the ingrowing tissue. In addition, the high degree of porosity allow the accommodation of a large number of cells and ensures a high rate of cell growth. Also, for tissue ingrowth, vascularization, and diffusion of nutrients, pore diameter much larger than the implanted cell diameter is required as well as a structure of interconnection between pores to form a pore network (p. 10, first paragraph).

Leong discloses that the “three dimensional foams are designed to mimic the natural connective tissues of the body” (p. 8, first paragraph).

Applicants submit that those of skill in the art would not be motivated to combine Humes with Leong in order to produce the invention recited in any of the independent or dependent claims, because the teachings of Humes are directly *contrary* to the teachings of Leong. As discussed above, Humes discloses capsules that are specifically designed to *prevent* cells from passing therethrough, e.g., “macrophages and lymphocytes, which if allowed to pass through the pores from the blood stream into the hollow fiber may be detrimental to the viability of the cells enclosed therein.” In contrast, Leong is directed to foams that are designed to mimic connective tissue, and have pore diameters that are “much larger than the implanted cell diameter” in order to *allow* for tissue ingrowth, vascularization, and diffusion of nutrients. While Humes specifically teaches away from methods and structures that allow cells to penetrate a capsule, Leong specifically teaches that large pore diameters are *required*. Thus, Humes and Leong are incompatible with each other, and those of skill in the art would not be motivated to combine their teachings for any reason, let alone to produce the claimed invention.

Conclusion

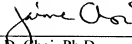
In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

No fee is believed to be due with the filing of this response. However, please charge any required fee, or any overpayment, to Jones Day Deposit Account No. 50-3013.

If the Examiner believes it would be useful to advance prosecution, the Examiner is invited to telephone the undersigned at (858) 314-1200.

Respectfully submitted,

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By: Jaime R. Choi, Ph.D. Reg. No. 59,198
For: Nicola A. Pisano Reg. No. 34,408
And: Anthony M. Insogna Reg. No. 35,203

JONES DAY
222 East 41st Street
New York, New York 10017
(858) 314-1200